

HEALTH

PUBLIC HEALTH EMERGENCY PREPAREDNESS – STATE’S AUTHORITY TO RATION VENTILATORS DURING PANDEMIC – PHYSICIAN IMMUNITY

December 28, 2015

The Honorable Terri L. Hill, M.D.

The Maryland House of Delegates

There is growing concern among health experts across the globe that a large-scale influenza pandemic, like the “Spanish Flu” that last century killed tens of millions of people worldwide, may occur in the coming years. If such a pandemic occurs, there may not be sufficient resources to care for all of the patients who arrive at the hospital in respiratory distress. For example, mechanical ventilators are typically used to help patients breathe under these circumstances, but experts predict that there will not be enough ventilators to meet demand. *See, e.g., All Hazards Medical Preparedness and Response: Hearing Before the Senate Subcomm. on Bioterrorism and Public Health Preparedness*, 109th Cong. 22 (2006) (testimony of Thomas Inglesby, Center for Biosecurity, Univ. of Pittsburgh Med. Ctr.). You have asked two questions related to the allocation of ventilators during an influenza pandemic:

In planning for an influenza pandemic or similar outbreak that causes widespread and severe respiratory distress, what is the extent of the State’s legal authority to adopt criteria for allocating ventilators?

If the State adopted criteria for allocating ventilators that might require a hospital or clinician to remove a patient from a ventilator in order to make the ventilator available to another individual, would the hospital or clinician risk liability for doing so?¹

¹ We understand you to be asking about criteria that would be *mandatory* for hospital physicians and staff. Our survey of other states’ efforts at pandemic preparedness, however, indicates that most, if not all, contemplate non-binding criteria. *See infra* note 2. We will base our analysis on the assumption that the criteria adopted would be mandatory

You do not ask, and we do not discuss, what criteria should be used to decide who will have access to a ventilator or whether it is morally or ethically appropriate to remove a struggling patient from a ventilator to make room for another patient with a better chance of survival. These issues are not for us to decide. Instead, we will predict as best as we can what the courts might decide about the State's legal authority in this context.

In our view, a court would likely find that the Governor has authority to adopt criteria for the allocation of ventilators pursuant to his power to order public health officials to ration scarce medical resources during a declared emergency under the Catastrophic Health Emergencies Act. *See* Md. Code Ann., Public Safety ("PS") § 14-3A-03(b)(2)(i). The Governor could enlist the Department of Health and Mental Hygiene ("DHMH" or the "Department") to assist in formulating those criteria in advance, but we doubt the Department would be able to implement the criteria absent an executive order from the Governor under the Act. If the State adopts allocation criteria under this statute, a hospital or clinician would have immunity from liability for actions taken in accordance with those criteria.

In drafting the criteria, care must be taken to ensure that the criteria do not run afoul of constitutional limitations. Although we doubt that a court would conclude that the State is constitutionally prohibited from adopting allocation criteria if there is a dire shortage of ventilators during a health emergency, substantive and procedural due process may well limit the State's policy choices in this area. To reduce the risk that the criteria would violate due process, the criteria should (a) be implemented only when there is no other choice, (b) reduce the likelihood that individuals with a significant chance of survival will be removed from a ventilator without consent, and (c) afford procedural protections to patients who are removed from a ventilator or denied ventilator use.

I

Background

Mechanical ventilators are machines that help patients breathe when they are not able to do so on their own. They are critical tools for the treatment of individuals with respiratory illnesses, including

but will identify those places where the analysis might diverge if the criteria are voluntary.

severe influenza. Typically, “all patients who have a medical need for and can benefit from mechanical ventilation and who consent to treatment (or have the concurrence of a surrogate) are provided this type of care.” Ventilator Document Workgroup, Centers for Disease Control and Prevention, *Ethical Considerations for Decision Making Regarding Allocation of Mechanical Ventilators during a Severe Influenza Pandemic or Other Public Health Emergency*, at 8 (2011), www.cdc.gov/about/pdf/advisory/ventdocument_release.pdf. In “routine clinical circumstances,” ventilators are typically allocated on a “first come, first served” basis. *Id.* at 9.

As long as a patient continues to need the ventilator, the normal rule is that the patient will not be withdrawn from the ventilator without consent. In everyday clinical practice, “[p]hysicians do not unilaterally withdraw mechanical ventilation against a patient’s wishes in order to provide it to someone else.” Douglas B. White et al., *Who Should Receive Life Support During a Public Health Emergency? Using Ethical Principles to Improve Allocation Decisions*, 150 *Annals of Internal Med.* 132, 132 (2009). This practice is consistent with the traditional standard of care in the medical profession. See *Katsetos v. Nolan*, 170 Conn. 637, 654 (1976) (“[A] physician is under the duty to give his patient all necessary and continued attention as long as the case requires it” (internal quotation marks omitted)). Thus, under normal circumstances, “[i]f a provider removes a ventilator from a patient against the patient’s or the patient’s family’s wishes and with foreseeable harm or death likely to result, the provider may be vulnerable to charges of negligent homicide, manslaughter, or criminal negligence” as well as to civil liability. Darren Mareiniss et al., *ICU Triage: The Potential Legal Liability of Withdrawing ICU Care During a Catastrophic Event*, 6:6 *Am. J. of Disaster Med.* 329, 333, 334 (2011).

The normal practice, however, assumes an adequate supply of ventilators, when decisions about one patient’s treatment do not affect other patients’ chances of survival. During an influenza pandemic, hospitals may instead be faced with an unprecedented shortage. The United States maintains a stockpile of ventilators far short of those needed to respond to a pandemic-scale public health emergency. See Lewis Robinson et al., *Mechanical Ventilators in U.S. Acute Care Hospitals*, 4 *Disaster Med. and Pub. Health Preparedness* 199 (2010). As the United States Centers for Disease Control and Prevention (“CDC”) has estimated, “[i]n a typical city [during] a pandemic of moderate duration,” influenza patients “would be predicted to require . . . 198% of all available

ventilators.” Inglesby, *supra*, at 1. In addition, hospital staff capable of operating ventilators may be in short supply during a health emergency, further exacerbating the shortage of the ventilators themselves. See John L. Hick et al., *Allocating Scarce Resources in Disasters: Emergency Department Principles*, 59 *Annals of Emergency Medicine* 177, 179 (2012). Hospitals would thus be forced to decide which patients are to receive a ventilator and which are not. Under those conditions, whether to continue the ventilation of one patient may well be a life-or-death decision, both for the patient and for others awaiting access to a ventilator.

This suggests that during a pandemic it might be “necessary to re-evaluate the ethical considerations that govern the usual provision of care.” CDC Ventilator Document Workgroup, *supra*, at 8. If ventilators are allocated according to the principle of “sickest first,” or based on the principle of “first come, first served,” then limited resources might be given to patients “who ultimately are too sick to survive,” while other patients, “who may have a much better prognosis if they receive intensive care, will not have access to it.” *Id.* at 9. Similarly, because some patients who are on ventilators will not respond to treatment, medical professionals might be forced to make decisions “regarding whether patients should be removed from ventilators if this is needed to free up ventilators for others who may have a much better chance of recovery.” *Id.*

Many States, health care professionals, and federal agencies are considering how to respond to the potential shortage of ventilators during an influenza pandemic. One possibility is to continue to apply the principle of “first come, first served” in disaster situations; that would seem to be an easily-administered, value-neutral way of allocating scarce resources. Other scholars and policy experts suggest that health care providers and the State should instead try to save as many lives as possible by allocating scarce resources to the patients who are most likely to benefit. *Id.* at 12. Finally, some scholars assert that the distribution of scarce resources during a pandemic should be governed by the “life cycle” or “fair innings” principle, which in practice “gives relative priority to younger individuals over older individuals.” *Id.* at 15. This is based on the premise that “it is a valuable goal to give individuals equal opportunity to pass through the stages of life.” White, *supra*, at 135.

At the state level, New York has taken the lead in developing criteria for the allocation of ventilators during a pandemic by

issuing draft guidelines in 2007 and publishing its final report in 2015. *See* New York State Dep’t of Health and Task Force on Life and the Law, *Ventilator Allocation Guidelines* (Nov. 2015) (“New York Guidelines”). New York’s report recommends “voluntary, non-binding guidelines” for health care facilities to follow when a flu pandemic outstrips the available supply of ventilators. *Id.* at 8. These guidelines prioritize “sav[ing] the most lives” and advise that hospitals should provide ventilators to patients who have the best chance of survival with the support of a ventilator based on certain objective clinical criteria for assessing patient prognoses. *Id.* at 12. By contrast, “[p]atients with the highest likelihood of survival *without* medical intervention, along with patients with the smallest likelihood of survival *with* medical intervention, have the *lowest* [priority for] access to ventilator therapy.” *Id.* (emphasis in original).

New York’s guidelines also recommend that hospitals reevaluate all patients on ventilators every 48 and 120 hours to determine whether those patients are benefitting from the treatment. *Id.* at 14-15, 61-67. A patient who is not improving will be withdrawn from the ventilator if there is another patient waiting with a significantly greater chance of survival. *Id.* at 14-15, 68-69. The guidelines, however, expressly rejected an approach under which a patient would be removed from a ventilator, even if that patient were improving, whenever a new patient arrived with a better chance of survival. *Id.* at 48-49. The Task Force concluded that such an approach would not give patients “a sufficient trial on the ventilator to determine whether the patient was benefitting from the treatment” and would “evoke[] an ICU war of all against all.” *Id.*

A number of other states have followed New York’s example by creating their own ventilator allocation criteria.² Maryland has also recently begun considering the issue. *See* Elizabeth L. Daugherty Biddison et al., *The Community Speaks: Understanding Ethical Values in Allocation of Scarce Lifesaving Resources During Disasters*, 11 *Annals of the Am. Thoracic Soc’y* 777 (2014). In 2013, the Johns Hopkins Medicine Office of Emergency

² New York’s final report includes a comprehensive list of other states’ ventilator allocation guidelines, including Alabama, Alaska, Colorado, Florida, Indiana, Iowa, Kansas, Minnesota, New Mexico, South Carolina, Texas, Utah, and Wisconsin. *See* New York Guidelines at 51 n.99. As best as we can tell, these other state plans also seem to contemplate voluntary, non-binding guidance rather than mandatory criteria.

Management, the Johns Hopkins Berman Institute for Bioethics, and the Center for Health Security at the University of Pittsburgh Medical Center collaborated on a pilot study aimed at developing “specific deliberative democratic procedures that could ultimately be used in a statewide process to inform a Maryland framework for allocating scarce healthcare resources during disasters.” *Id.* at 777. These groups hope to encourage a large-scale public engagement process that will result in “a common framework in Maryland for the allocation of scarce healthcare resources during disasters.” *Id.* at 783. It is our understanding that this ongoing effort prompted your opinion request to resolve some of the legal uncertainty surrounding emergency preparedness in Maryland.

II

Analysis

A. *The State’s Power to Set Ventilator Allocation Criteria Under the Maryland Catastrophic Health Emergencies Act.*

Your first question is whether the State has statutory authority to adopt binding criteria for the allocation of mechanical ventilators during a flu pandemic. We believe that it does, and that the power to do so is vested primarily in the Governor, with the Department of Health and Mental Hygiene holding certain complementary powers.

1. **The Governor’s Power Under Title 14 of the Public Safety Article**

In general, the Governor has significant authority to respond to a declared emergency. *See* PS § 14-107(d). For example, if “necessary in order to protect the public health, welfare, or safety,” the Governor may “suspend the effect of any statute or rule or regulation of an agency of the State or a political subdivision” or order the “evacuation of all or part of the population from a stricken or threatened area” of the State. PS § 14-107(d)(1)(i), (ii). This general power applies to a wide range of different types of emergencies, including “a public health catastrophe.” PS § 14-101(c)(2).

More importantly for our purposes, the Governor also has broad authority to respond to certain health emergencies under Maryland’s Catastrophic Health Emergencies Act. This statute applies when the Governor declares a “catastrophic health emergency,” defined as “a situation in which extensive loss of life

or serious disability is threatened imminently because of exposure to a deadly agent.” PS § 14-3A-01(b). “[D]eadly agent,” in turn, means “anthrax, ebola, plague, smallpox, tularemia, or other bacterial, fungal, rickettsial, or viral agent, biological toxin, or *other biological agent capable of causing extensive loss of life or serious disability.*” PS § 14-3A-01(c)(1) (emphasis added). The Act thus encompasses the type of flu pandemic that you have posited. The law was passed in 2002 as part of an “overall anti-terrorism package” following the terrorist attacks of September 11, 2001. Floor Report on H.B. 296, 2002 Leg., Reg. Sess., at 8 (2002); *see also* 2002 Md. Laws, ch. 1. It was based in part of the Model State Emergency Powers Act (“Model Act”), which was drafted by the Center for Law and the Public’s Health as a template for States considering legislation on the topic. *See The Model State Emergency Health Powers Act* (Ctr. for Law & the Public’s Health, Georgetown and Johns Hopkins Universities 2001), *available at* www.publichealthlaw.net/MSEHPA/MSEHPA.pdf (last visited Dec. 10, 2015).

Under the statute, the Governor may issue a proclamation that declares a catastrophic health emergency and authorizes him to exercise a broad array of governmental powers targeted to problems related to the emergency. PS § 14-3A-02. The Governor, for instance, may “require individuals to submit to vaccination or medical treatment” and “require individuals to go to and remain in places of isolation or quarantine.” PS § 14-3A-03(b)(3)(ii), (iv). The Governor may also order the Secretary of Health and Mental Hygiene or other designated official to:

control, restrict, or regulate the use, sale, dispensing, distribution, or transportation of anything needed to respond to the medical consequences of the catastrophic health emergency by:

- (i) *rationing or using quotas*;
- (ii) creating and distributing stockpiles;
- (iii) prohibiting shipments;
- (iv) setting prices; or
- (v) taking other appropriate actions.

PS § 14-3A-03(b)(2) (emphasis added). The question is whether this statutory language grants the Governor authority to set criteria for the allocation of ventilators.

When interpreting statutes, we “begin[] with the plain language of the statute, and ordinary, popular understanding of the English language dictates interpretation of its terminology.” *Maryland Econ. Dev. Corp. v. Montgomery County*, 431 Md. 189, 199 (2013) (citation and quotation marks omitted). But “the plain language must be viewed within the context of the statutory scheme to which it belongs, considering the purpose, aim, or policy of the Legislature in enacting the statute.” *Employees’ Ret. Sys. of Baltimore v. Dorsey*, 430 Md. 100, 113 (2013) (citations and internal quotation marks omitted). After all, the goal of statutory interpretation “is always to discern the legislative purpose, the ends to be accomplished, or the evils to be remedied by a particular provision.” *People’s Ins. Counsel Div. v. Allstate Ins. Co.*, 408 Md. 336, 351 (2009) (internal quotation marks omitted).

In our opinion, the Governor’s broad powers during a catastrophic health emergency include allocating access to ventilators. Following the proclamation of a catastrophic health emergency, “[t]he Governor may order the Secretary or other designated official to control, restrict, or regulate the use” and “distribution” of “anything needed to respond to the medical consequences of the catastrophic health emergency” by “rationing or using quotas” or “taking other appropriate actions.” PS § 14-3A-03(b)(2). During a pandemic, ventilators will likely be “needed to respond to the medical consequences of the catastrophic health emergency” and thus subject to § 14-3A-03(b)(2).

Moreover, the power to “control, restrict, or regulate the use” of such an item “by rationing” encompasses the power to allocate scarce medical resources. The verb “to ration” has been defined as “to distribute or divide (as commodities in short supply) in an equitable manner or so as to achieve a particular object (as maximum production of particular items).” Webster’s Third New International Dictionary 1885 (1993). That definition would seem to fit comfortably the ventilator allocation criteria we are discussing here. The definition is also fairly similar to the definition of “allocate,” which includes “to distribute or to divide and distribute according to relative contribution to an objective whether on an equal, proportional, or judiciously calculated basis.” *Id.* at 57; see also *Medstar Health v. Maryland Health Care Comm’n*, 391 Md. 427, 431 (2006) (using “allocation” and “rationing” synonymously); *Gallagher’s Steak House v. Bowles*, 142 F.2d 530, 534 (2d Cir. 1944) (holding that presidential power to “allocate” items during wartime included power to “ration”); Michael D. Reagan, *Health Care Rationing and Cost Containment*

Are Not Synonymous, 9 Policy Studies Review 219, 220-23 (Winter 1990) (concluding that rationing in the health care context means the distribution of a scarce resource, such as a single dialysis machine in a rural town, among individual claimants based on principles of equity). Indeed, an informational chart from the bill file confirms that the rationale for this provision was, among other things, to “permit[] emergency allocation procedures to be implemented.”³ H.B. 296, 2002 Leg., Reg. Sess., Comparison Between Proposed Catastrophic Public Health Emergency Legislation and Current Maryland Law. The Governor thus has statutory authority to adopt allocation criteria.

It is less clear, however, whether the General Assembly intended merely to authorize the use of allocation criteria that would govern which patients receive ventilators in the first instance or whether it also intended to authorize criteria, like New York’s, for reassessing and withdrawing patients from ventilators to make room for others. Although the language in § 14-3A-03(b)(2)(i) seems to apply equally to both situations, it would be far more controversial to remove a patient from a ventilator than to withhold treatment in the first instance. *See* Phillip Levin & Charles Sprung, *Withdrawing and Withholding Life-Sustaining Therapies are not the Same*, 9 Critical Care 230 (2005). Moreover, the General Assembly provided procedural protections for individuals subject to isolation and quarantine orders issued by the Governor under the Act, *see* PS § 14-3A-05(c)(1), and yet did not provide the same for patients facing the withdrawal of potentially life-saving treatment. If the Legislature had intended to authorize criteria providing for the removal of ventilators, one might have expected it to enact corresponding procedural protections.

Although these considerations give us pause, it is not clear that there is any *legal* distinction between withholding and withdrawing medical treatment. We concluded in a prior opinion

³ The Model Act, which served as the template for this provision of the Maryland statute, also explicitly refers to the “allocation” of scarce resources during an emergency. We recognize that the Model Act uses the terms “rationing” and “allocation” separately in describing the ways in which a public health authority might regulate access to medical products, *see* Model Act, *supra*, at 24, which could imply that the terms have different meanings. But it is more likely that the General Assembly omitted “allocation” from the statute because the term “rationing” already included both concepts, not because of any intent to exclude one and include the other. A contrary reading would “obscure the substance” of the law by putting an “overemphasis upon the label attached” to the Governor’s power. *Gallagher’s Steak House*, 142 F.2d at 534.

that terminally ill or permanently comatose patients have a right to refuse life-sustaining treatment both by withholding consent in the first place and also by later revoking that consent. 73 *Opinions of the Attorney General* 162, 171-78 (1988). We reasoned that the “distinction” between withholding and withdrawing treatment “is more psychologically compelling than logically sound” and that “the line between active and passive conduct in the context of medical decisions is far too nebulous to constitute a principled basis for decisionmaking.” *Id.* at 171 (quoting *In re Conroy*, 98 N.J. 321, 370 (1985)). After all, “[w]hether necessary treatment is withheld at the outset or withdrawn later on, the consequence—the patient’s death—is the same.” *Id.* (quoting *In re Conroy*, 98 N.J. at 370); see also American Medical Association Code of Medical Ethics, *Opinion 2.20 – Withholding or Withdrawing Life-Sustaining Medical Treatment* (1996) (“There is no ethical distinction between withdrawing and withholding life-sustaining treatment.”); but see Mareiniss et al., *ICU Triage*, *supra*, at 334 (noting that there is usually no difference between withdrawing and withholding treatment when the decision is made by a patient, but when the decision is made against the patient’s wishes there may be a greater risk of liability if a patient is removed from treatment than if treatment is merely withheld).

The Court of Appeals too has stated that patients have a right to “refuse treatment and to withdraw consent to treatment once begun,” without drawing any distinction between the two concepts. See *Mack v. Mack*, 329 Md. 188, 210 (1993). But the Court has also questioned in dicta whether the withholding and withdrawal of treatment are legally the same. See *In re Riddlemoser*, 317 Md. 496, 504 n.5 (1989). *Riddlemoser* involved whether a circuit court had the power under a statute permitting courts to “authorize” medical treatment for disabled persons to withhold or withdraw life-sustaining treatment from a permanently comatose patient. *Id.* at 504. Although the Court dismissed the appeal as moot and did not reach the merits, it observed in a footnote that “the power to withhold treatment and the power to withdraw treatment are separate and distinct.” *Id.* at 504 n.5.

In any event, neither the Court of Appeals opinion in *Riddlemoser* nor our own prior opinion directly answers the relevant question here, namely, whether the General Assembly intended to authorize emergency allocation criteria that cover both the withholding and withdrawal of ventilators. For that, we return to the text of the statute, which does not draw any distinction between the concepts; both withholding and withdrawing

ventilators constitute “rationing.” *See* PS § 14-3A-03(b)(2)(i). Moreover, the primary purpose of the Catastrophic Health Emergencies Act is to help save lives, and granting the Governor the authority to set allocation guidelines for the initial provision of ventilators while prohibiting their withdrawal and reallocation would not fully effectuate that purpose. Such a plan would bind health care providers to a state of affairs where patients with hopeful prognoses are dying while those unlikely to survive even with ventilator treatment exhaust all of the available resources. *See* CDC Ventilator Document Workgroup, *supra*, at 21. Thus, although the Legislature could enact legislation clarifying the issue, we think a court is more likely to conclude that the current statute grants the Governor authority to set allocation criteria both for access to, and withdrawal from, ventilators during a flu pandemic.

It is important to emphasize, though, that the Governor’s power to ration supplies is not unlimited. The Governor’s authority is triggered only when he has properly declared a catastrophic health emergency, PS § 14-3A-03(a), and he may impose the allocation criteria only as to something “needed to respond to the medical consequences of the catastrophic health emergency.” PS § 14-3A-03(b)(2). And, as discussed further below, there are also constitutional limits on his authority. But we conclude that, as a matter of law, the General Assembly has granted the Governor the authority to establish criteria governing both access to, and reallocation of, ventilators.⁴

2. DHMH’s Power to Establish Treatment Protocols Under Title 18 of the Health-General Article

We next consider whether DHMH has separate authority to implement allocation criteria without an order from the Governor under § 14-3A-03. To some extent, this is an academic question; the Department is subject to the Governor’s control and the two would presumably coordinate with each other on any emergency response. But there is nonetheless an argument that the Department has authority of its own. Among the Department’s emergency powers is the power to “require health care facilities to develop and implement contingency plans addressing . . . [t]reatment and decontamination protocols” as well as “any other area that the Secretary determines is necessary to assist in the early detection

⁴ In addition, if any State laws conflict with the allocation criteria, the Governor has the power to “suspend the effect of any statute or rule or regulation of an agency of the State or a political subdivision.” PS § 14-107(d)(1)(i).

and treatment of an individual exposed to a deadly agent.” Md. Code Ann., Health-Gen. (“HG”) § 18-903(a)(1). DHMH is also charged with “publishing protocols to assist health care practitioners in developing plans to respond to a catastrophic health emergency” and “[m]ay, if necessary, require health care practitioners to implement” those protocols. HG § 18-903(b).

In our view, however, a court would more likely hold that the Department lacks authority to establish binding allocation criteria on its own. The relevant provisions of the Health-General Article were enacted as part of the same legislation that set forth the Governor’s powers in the event of a catastrophic health emergency, *see* 2002 Md. Laws, ch. 1, and the General Assembly in that legislation specifically reserved for the Governor the sensitive power to ration scarce resources during a catastrophic health emergency. *See* PS § 14-3A-03. We doubt a court would read into the Department’s general power to publish emergency protocols the more specific rationing power that the General Assembly granted to the Governor. The Governor could certainly request that the Department help develop the allocation criteria in advance and order the Secretary to implement the criteria during a declared emergency, but we do not believe the Department has the authority to issue mandatory criteria on its own.⁵

B. Constitutional Limits on the Governor’s Authority to Set Allocation Criteria

Although we conclude that the Governor has statutory authority to set allocation criteria for ventilators during a pandemic, he must exercise that authority within constitutional boundaries. For example, the Equal Protection Clause would prohibit the use of criteria that draw arbitrary lines among different groups of people or discriminate against protected classes of individuals. *See* Necia B. Hobbes, Note, *Out of the Frying Pan Into the Fire: Heightened Discrimination & Reduced Legal Safeguards When Pandemic Strikes*, 72 U. Pitt. L. Rev. 779 (2011).⁶ The Fourth Amendment

⁵ The Department likely could, however, issue non-binding ventilator criteria as an exercise of its authority under HG § 18-903(b) to publish “protocols.” It might also be able to make those criteria binding for hospitals, so long as it does not intrude upon those powers that the General Assembly has already conferred upon the Governor.

⁶ There are also federal statutes prohibiting certain types of discrimination on the basis of age and disability. *See, e.g.*, 42 U.S.C.

restrictions on unreasonable searches and seizures might also apply if the criteria require doctors to conduct invasive tests that they otherwise would not perform in the course of treatment. *See* New York Guidelines at 211.⁷

The constitutional limitation most relevant here is the Fourteenth Amendment of the U.S. Constitution, which provides that “[n]o state shall . . . deprive any person of life, liberty, or property, without due process of law.”⁸ U.S. Const., amend. XIV, § 1. This constitutional safeguard includes both a procedural and a substantive component. *County of Sacramento v. Lewis*, 523 U.S. 833, 845-46 (1998). Procedural due process ensures that the government will not deprive individuals of life, liberty, or property without affording them procedures that comport with notions of “fundamental fairness,” while substantive due process defends against the arbitrary “exercise of [government] power without any

§§ 12132, 12182 (Americans with Disabilities Act); 42 U.S.C. § 6102 (Age Discrimination Act of 1975). Although we have not considered how these laws might apply in the context of a flu pandemic, State officials involved in drafting any criteria should be aware of them.

⁷ The taking of a blood sample, urine sample, or buccal swab qualifies as a search or seizure when carried out within the context of law enforcement or public safety. *See Maryland v. King*, 133 S. Ct. 1958, 1969 (2013) (buccal swab); *Schmerber v. California*, 384 U.S. 757, 767-71 (1966) (blood); *Skinner v. Railway Labor Executives’ Assn.*, 489 U.S. 602, 616-17 (1989) (breathalyzer and urine sample). Although we are not aware of any cases evaluating medical procedures under the Fourth Amendment outside of that context, a court would likely evaluate the reasonableness of the diagnostic tests at issue here under the more flexible balancing test that applies to administrative searches and the “community caretaking function.” *See 100 Opinions of the Attorney General* 3, 22-27 (2015) (providing an overview of administrative searches and the “special needs” exception to the warrant and probable cause requirements); *Wilson v. State*, 409 Md. 415, 439 (2009) (evaluating officer’s exercise of community caretaking function by reasonableness standard). We have not considered the issue in detail, but we suspect that the State could fashion an allocation regime that is consistent with the Fourth Amendment.

⁸ The due process protections in the Maryland Constitution are “usually read *in pari materia* with the federal analogue.” *In re Ryan W.*, 434 Md. 577, 608 (2013). For ease of analysis, we will therefore focus on federal law, but it is possible that Maryland courts could construe the Maryland Constitution more broadly than its federal counterpart. *See, e.g., Koshko v. Haining*, 398 Md. 404, 444 n.22 (2007) (“We have not hesitated, where deemed appropriate, to offer a different interpretation of the Maryland provision.”).

reasonable justification,” regardless of how many procedural protections have been afforded. *Id.* at 845-46. We will consider if and how these components of due process constrain the Governor’s power to issue allocation criteria for ventilators in a flu pandemic.

1. State Action

The Fourteenth Amendment, by its terms, only forbids arbitrary action on the part of the State. The threshold inquiry for all due process questions is thus whether there is “state action,” that is, whether the procedural or substantive deprivation at issue is fairly attributable to the government. *See, e.g., Blum v. Yaretsky*, 457 U.S. 991, 1002-03 (1982). “The purpose of this requirement is to assure that constitutional standards are invoked only when it can be said that the State is *responsible* for the specific conduct of which the plaintiff complains.” *Id.* at 1004 (emphasis in original).

The state action component of the due process inquiry is not present when a private actor is merely acting in accordance with a regulatory scheme created by the government. *See American Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 50 (1999) (holding that plaintiffs could not bypass the state action requirement by “characteriz[ing] their claim as a ‘facial’ or ‘direct’ challenge” on government regulations). Instead, the Supreme Court has emphasized that state action “requires *both* an alleged constitutional deprivation caused by the exercise of some right or privilege created by the State or by a rule of conduct imposed by the State or by a person for whom the State is responsible, *and* that the party charged with the deprivation must be a person who may fairly be said to be a state actor.” *Id.* (emphasis in original; internal quotation marks omitted).

There are some circumstances, however, under which a private entity is properly characterized as a state actor. State action exists when “there is a sufficiently close nexus between the State and the challenged action of the regulated entity so that the action of the latter may be fairly treated as that of the State itself.” *Jackson v. Metropolitan Edison Co.*, 419 U.S. 345, 351 (1974). As is relevant here, “a State normally can be held responsible for a private decision only when it has exercised coercive power or has provided such significant encouragement, either overt or covert, that the choice must in law be deemed to be that of the State.” *Blum*, 457 U.S. at 1004; *see also Sullivan*, 526 U.S. at 52.

It is our understanding that the final decision to withhold a ventilator from a patient or to remove a patient from a ventilator will typically be made by private doctors in private medical facilities. The Due Process Clause will thus apply only to the extent those private medical decisions can be attributed to the Government. As we understand your question, however, the State would be issuing *mandatory* criteria governing the allocation of the available ventilators. If the State is requiring doctors to make allocation decisions and the State-issued criteria governing those decisions are binding, a court might well conclude that the State is exercising sufficient “coercive power” to qualify as state action. *Blum*, 457 U.S. at 1004. This is especially true given that the Catastrophic Health Emergencies Act imposes criminal penalties on persons who “knowingly and willfully fail to comply with an order, requirement, or directive issued under” the Act. PS § 14-3A-08(a).

The Supreme Court’s decision in *Blum* is instructive. In that case, a class of Medicaid patients alleged that their nursing homes improperly transferred them to a lower level of care without first providing notice and an opportunity for a hearing. *Blum*, 457 U.S. at 993-96. Although the nursing homes were private entities, the plaintiffs claimed that the State effectively compelled the “transfer of Medicaid patients” by requiring health care providers to fill out a particular State-issued assessment form when making transfer decisions. *Id.* at 1005. The Supreme Court held that there was no state action because the State did “not require the nursing homes to rely on the forms in making discharge or transfer decisions”; rather, the ultimate decisions about whether to move the patients “turn[ed] on medical judgments made by private parties according to professional standards that are not established by the State.” *Id.* at 1008. In other words, “[t]he rule of decision” was “nothing more than a medical judgment.” *Id.* at 1012 (White, J., concurring in the judgment).

Blum thus holds that state action does not exist when the government merely asks medical professionals to make decisions based on their private medical judgment, but it suggests that the result might be otherwise were the State to “affirmatively command” doctors to take certain actions under detailed mandatory criteria established by the State. *See id.* at 1005. Accordingly, depending on the specificity of the criteria and the extent to which they bind doctors in exercising their medical judgment, there might be state action in this context. If the final criteria are non-binding, it is less likely that the private physicians who choose to follow the criteria would be considered state actors for purposes of the

Fourteenth Amendment.⁹ See New York Guidelines at 209. We will assume that the Due Process Clause applies and consider whether its substantive and procedural components place any limits on the Governor's authority.

2. Substantive Due Process

The substantive component of the Due Process Clause protects individuals against "certain government actions regardless of the fairness of the procedures used to implement them," *Daniels v. Williams*, 474 U.S. 327, 331 (1986), and "provides heightened protection against government interference with certain fundamental rights and liberty interests," *Washington v. Glucksberg*, 521 U.S. 702, 720 (1997). It "forbids the government to infringe certain 'fundamental' liberty interests *at all*, no matter what process is provided, unless the infringement is narrowly tailored to serve a compelling state interest."¹⁰ *Reno v. Flores*, 507 U.S. 292, 302 (1993) (emphasis in original). In other words, if a liberty interest is fundamental, a governmental restriction on that

⁹ A patient might still argue that the conferral of immunity on health care providers encourages hospitals to follow voluntary guidelines and hence triggers the state action doctrine. There is some basis in the case law for questioning whether statutorily-conferred immunity is sufficient "encouragement" to render private medical decisions "state action" under the test laid out in *Blum*. See, e.g., *Goss v. Memorial Hosp. Sys.*, 789 F.2d 353, 356 (5th Cir. 1986) (conferral of statutory immunity on private medical peer review committee insufficient to render committee's incompetency finding the result of "state action"); *White v. Scrivner Corp.*, 594 F.2d 140, 143 (5th Cir. 1979) (statute insulating merchants from liability for detaining suspected shoplifters does not make merchant's holding of plaintiff "state action").

¹⁰ A different test applies to so-called "executive" actions. *Lewis*, 523 U.S. at 846. While legislative acts that implicate fundamental rights are subject to the normal strict scrutiny test, an executive act only violates substantive due process if it "shocks the conscience." *Id.* at 846-47. However, the fact that the allocation criteria in question here would be set through a regulation or executive order does not mean the action would be executive in character. As one federal court has clarified, "[l]egislative acts" generally include "laws and broad-ranging executive regulations" that "apply to a large[] segment of—if not all of—society," whereas "[e]xecutive acts . . . characteristically apply to a limited number of persons (and often to only one person)," and usually "arise from the ministerial or administrative activities of members of the executive branch." *McKinney v. Pate*, 20 F.3d 1550, 1557 n.9 (11th Cir. 1994) (emphasis added).

interest must pass strict scrutiny. If not, the regulation will be constitutional as long as it passes the rational basis test, *i.e.*, has a rational relation to any legitimate state interest.

The Constitution, however, does not specify the fundamental rights that receive heightened protection under the Due Process Clause, and the challenge for courts is to identify which rights will qualify as fundamental. The Supreme Court described that challenge in *Glucksberg*:

[W]e have always been reluctant to expand the concept of substantive due process because guideposts for responsible decisionmaking in this uncharted area are scarce and open-ended. By extending constitutional protection to an asserted right or liberty interest, we, to a great extent, place the matter outside the arena of public debate and legislative action. We must therefore exercise the utmost care whenever we are asked to break new ground in this field, lest the liberty protected by the Due Process Clause be subtly transformed into the policy preferences of the Members of this Court.

521 U.S. at 720 (internal quotations marks and citations omitted).

Despite these difficulties, the Supreme Court in *Glucksberg* established at least a general framework for identifying fundamental rights. Under this framework, rights are fundamental if “deeply rooted in [our] Nation’s history and tradition” and “implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if they were sacrificed.” *Id.* at 721 (internal quotation marks and citations omitted). The *Glucksberg* test also requires a “careful description” of the right at issue before considering whether that right is “deeply rooted.” *Id.* In theory, this ensures that the Court conducts its inquiry at the correct level of specificity, without defining the potential right too broadly or too narrowly. “[T]he description of the right is of crucial importance—too broad and a right becomes all-encompassing and impossible to evaluate; too narrow and a right appears trivial.” *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 716 (D.C. Cir. 2007) (en banc) (Rogers, J., dissenting).

The Supreme Court's decision in *Glucksberg* provides an example of how this test works in practice. The plaintiffs there challenged the State of Washington's statute prohibiting assisted suicide, claiming that they had a fundamental right "to choose a humane, dignified death." *Glucksberg*, 521 U.S. at 722. The Court, however, explained that fundamental rights could not be "deduced from abstract concepts of personal autonomy." *Id.* at 725. The Court instead articulated the question as "whether the 'liberty' specially protected by the Due Process Clause includes a right to commit suicide which itself includes a right to assistance in doing so." *Id.* at 723. After setting forth this "careful description," the Court observed that, "for over 700 years, the Anglo-American common-law tradition has punished or otherwise disapproved of both suicide and assisting suicide." *Id.* at 711. Accordingly, the Court ultimately concluded that there was no fundamental right to commit suicide rooted in our Nation's traditions. *Id.* at 728.

In more recent years, however, the Supreme Court appears to be moving away from the *Glucksberg* framework. The Court, in holding that same-sex couples may not be denied the fundamental right to marry, stated that the identification and protection of fundamental rights "has not been reduced to any formula," and explicitly questioned the usefulness of tradition in identifying such rights. *Obergefell v. Hodges*, 135 S. Ct. 2584, 2598 (2015) (internal quotation marks omitted); see also *Lawrence v. Texas*, 539 U.S. 558, 572 (2003). The Court instead explained that the Framers "entrusted to future generations a charter protecting the right of all persons to enjoy liberty as we learn its meaning." *Obergefell*, 135 S. Ct. at 2598. The Court also criticized *Glucksberg*'s "careful description" requirement, emphasizing that to define the liberty interest at issue in such a "circumscribed manner . . . is inconsistent with the approach this Court has used in discussing other fundamental rights, including marriage and intimacy." *Id.* at 2602. Chief Justice Roberts even suggested that the Court's opinion in *Obergefell* "effectively overrules *Glucksberg*." 135 S. Ct. at 2621 (Roberts, C.J., dissenting).

a. Defining the Fundamental Right

Given this uncertain legal background, it is difficult to predict how a court would characterize the potential right at issue here. The Supreme Court in *Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261 (1990), "strongly suggested" that a person in a persistent vegetative state has a fundamental liberty interest in

“refus[ing] unwanted lifesaving medical treatment,” *Glucksberg*, 521 U.S. at 720 (citing *Cruzan*, 497 U.S. at 278-79), but did not address or imply any fundamental right to *receive* particular medical treatment. The D.C. Circuit’s decision in *Abigail Alliance* comes closer to our issue because it involved an asserted right to receive medical care. Plaintiffs in that case sought access to potentially life-saving drugs that the U.S. Food and Drug Administration had not yet approved for medical use. *Abigail Alliance*, 495 F.3d at 701. While the dissent argued that the case involved a right “to preserve one’s life,” *id.* at 716, the majority characterized the issue as a “right to assume . . . enormous risks in pursuit of *potentially* life-saving drugs,” and found that no such right existed or was deeply rooted in our Nation’s traditions. *Id.* at 711 (internal quotations marks and citations omitted; emphasis in original). This decision provides some helpful guidance, but the court defined the right at issue with such focus on the particular regulatory scheme in question that the rationale cannot easily be imported into other contexts.

Although we cannot provide a definitive answer, it is at least possible that a court would recognize a fundamental right here. Courts have long recognized a “constitutionally protected liberty interest in bodily integrity.” *Williams v. Wilzack*, 319 Md. 485, 494-95 (1990). In fact, the Supreme Court has stated that “[n]o right is held more sacred, or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person” *Union Pacific Ry. Co. v. Botsford*, 141 U.S. 250, 251 (1891); *see also Cruzan*, 497 U.S. at 269 (“Every human being of adult years and sound mind has a right to determine what shall be done with his own body”) (internal quotation marks omitted); *In re Guardianship of L.W.*, 167 Wis. 2d 53, 67 (1992) (discussing a “common law right of self-determination and informed consent”); *Fosmire v. Nicoleau*, 75 N.Y.2d 218, 221 (1990) (stating that “a competent adult has the right to determine the course of his or her own medical treatment”); *Conroy*, 98 N.J. at 346, 348 (recognizing the “right of a person to control his own body” and “the common-law right to self-determination”); Abigail R. Moncrieff, *The Freedom of Health*, 159 U. Pa. L. Rev. 2209, 2238-39 (2011) (arguing that a fundamental right to “freedom of health” is emerging from Supreme Court precedents). In short, we think it possible that courts might recognize a fundamental right to make health care decisions free from government interference, or a right not to be withdrawn from potentially life-saving treatment without consent.

That said, these cases discussing bodily integrity involved decisions to refuse treatment; they do not necessarily support a right to demand treatment. Courts instead have consistently “rejected arguments that the Constitution provides an affirmative right of access to particular medical treatments.” *Abigail Alliance*, 495 F.3d at 710 (collecting cases). Moreover, in the context of a flu pandemic and a shortage of ventilators, access to medical care is a zero-sum proposition: One person’s right of access to medical treatment comes at the expense of another’s. A court thus might characterize the issue here as whether an individual has a right to a particular medical treatment *over someone else*. This way of posing the question answers itself; it cannot be that everyone has a constitutional right to receive treatment over everyone else. Nevertheless, taking all of these considerations into account, we think it is possible, but by no means certain, that a court would recognize a fundamental right in this context.¹¹

b. Narrow Tailoring

Even assuming there is a fundamental right infringed by the State’s allocation criteria, the Government may still restrict that right if the restriction is “narrowly tailored to serve a compelling state interest.” *Flores*, 507 U.S. at 302. The State undoubtedly has a compelling interest in saving lives. *See Cruzan*, 497 U.S. at 280 (observing that there “can be no gainsaying” that Missouri had an “interest in the protection and preservation of human life”). Moreover, the State also might have a compelling interest in providing for the fair and orderly allocation of scarce resources during a flu pandemic. *See, e.g., Husain v. Springer*, 494 F.3d 108, 125 (2d Cir. 2007) (identifying “the maintenance of public order” as a “compelling state interest”); *Grider v. Abramson*, 180 F.3d 739, 749 (6th Cir. 1999) (recognizing “compelling governmental

¹¹ There is also an argument that allocation criteria could implicate the constitutionally-protected interest in “life,” in that the withholding or withdrawal of treatment might lead to death. However, the denial of access to ventilator does not itself infringe that right because there is no guarantee that an individual would survive if given access to a ventilator or die if denied such access. As Attorney General Curran previously observed, “if death were eventually to occur, it would be the result, primarily, of the underlying disease.” 78 *Opinions of the Attorney General* 109, 124 (1993) (quoting *Conroy*, 98 N.J. at 351). The withdrawal of life-sustaining treatment essentially “allows the disease to take its natural course,” and thus the state does not *cause* the deprivation. *In re Guardianship of L.W.*, 167 Wis. 2d at 83 (quoting *Conroy*, 98 N.J. at 351).

interest in public safety and order”). The question is whether allocation criteria are “narrowly tailored” to achieve these goals.

The test for narrow-tailoring is difficult to meet, but, as the Court has emphasized in recent years, it is “not . . . fatal in fact.” *Adarand Constructors, Inc. v. Peña*, 515 U.S. 200, 237 (1995) (internal quotation marks and citation omitted); *see also Grutter v. Bollinger*, 539 U.S. 306, 326 (2003) (quoting *Adarand*). In general, a court will examine the restriction to gauge whether it is actually “necessary” to “advance[] the state’s interest,” whether it regulates more than necessary or significantly less than necessary to serve that interest, and whether there is another way of advancing the interest that involves a lesser infringement of the protected right. *Republican Party of Minnesota v. White*, 416 F.3d 738, 751 (8th Cir. 2005). “Although absolute necessity might not be required, the [Court] will require the government to show a close relationship between the classification and promotion of a compelling or overriding interest.” 3 Ronald D. Rotunda & John E. Nowak, *Treatise of Constitutional Law Substance and Procedure* § 18.3(a)(iii) (2012).

Whether the State’s allocation criteria satisfy strict scrutiny will of course depend on the content of the final executive order. The more directly that the criteria serve the government’s stated interests, the more likely the criteria will be upheld. At the very least, this means that the order should ensure that hospitals implement the allocation criteria only in the event of a major health emergency, like a pandemic or biological attack, when the hospital and the State have exhausted all of their other options and there is thus no less restrictive alternative to rationing ventilator access.

We also expect that a court conducting a narrow tailoring analysis would focus in particular on the criteria for withdrawing a patient from a ventilator. Although we have previously expressed doubts about whether there is any legal distinction between withholding and withdrawing medical treatment, *see 73 Opinions of the Attorney General* at 171, we have little doubt that the removal of a patient from a ventilator will seem to many individuals—and perhaps judges, *see Riddlemoser*, 317 Md. at 504 n.5—an intrusion that requires greater scrutiny. Therefore, the less likely that someone with a significant chance of survival would be removed from a ventilator without consent, the more likely that the criteria will pass strict scrutiny. The policy is also more likely to be upheld if, as under New York’s guidelines, patients are only removed from a ventilator if their condition has not sufficiently improved and other patients who are waiting have a significantly

better prognosis. *See* New York Guidelines at 68-69; *see also* American Medical Association Code of Medical Ethics, *Opinion 2.03 – Allocation of Limited Medical Resources* (1993) (noting that “only very substantial differences among patients are ethically relevant” and “the greater the disparities, the more justified the use of [allocation] criteria becomes”).

Ultimately, though, we doubt a court would rule that a State is constitutionally powerless to take steps during a pandemic to ensure the efficient allocation of scarce medical resources in an effort to save lives. The State’s interest in preserving life would weigh heavily against that result, *see Cruzan*, 497 U.S. at 280, especially where one person’s right of access to medical treatment comes at the expense of another’s. As the Supreme Court of New Jersey has observed, “When the patient’s exercise of his free choice could adversely and directly affect the health, safety, or security of others, the patient’s right of self-determination must frequently give way.” *Conroy*, 98 N.J. at 353; *see also Jacobson v. Massachusetts*, 197 U.S. 11 (1905) (holding that state could constitutionally require smallpox vaccinations). Furthermore, leaving it to each hospital to develop its own criteria for rationing access to ventilators might spell chaos, with families racing to find emergency rooms with the most favorable criteria. *See* Meir Katz, *Bioterrorism and Public Law: The Ethics of Scarce Medical Resource Allocation in Mass Casualty Situations*, 21 *Geo. J. Legal Ethics* 795, 797-99 (2008) (discussing possible public disorder during a catastrophic health emergency). State-issued allocation criteria, by contrast, will ensure consistency among medical providers and prevent a panicked rush for first access to a limited life-saving resource.

Finally, as the Supreme Court has warned, “extending constitutional protection to an asserted right or liberty interest . . . place[s] the matter outside the arena of public debate and legislative action.” *Glucksberg*, 521 U.S. at 720. Determining the fairest, most ethical way to allocate scarce resources during a catastrophic health emergency seems to be the kind of question that is best resolved through such public debate; indeed, the Maryland pilot study has already taken that approach. *See supra* at 164-65. We do not think a court would categorically prohibit the State from adopting criteria for the allocation of ventilators during a flu pandemic, even if those criteria provided that patients would be removed from ventilators under certain circumstances.

3. Procedural Due Process

The Due Process Clause also prohibits the government from abridging any constitutionally-protected “liberty” or “property” interests without affording sufficient procedural safeguards. *See Mathews v. Eldridge*, 424 U.S. 319, 332 (1976). This procedural component of due process is intended to protect persons from the “mistaken or unjustified deprivation of life, liberty, or property.” *Carey v. Piphus*, 435 U.S. 247, 259 (1978). Even if there is no substantive due process right at stake here, a patient may still be entitled to procedural protections. “Unlike substantive due process rights, which are founded upon ‘deeply rooted notions of fundamental personal interests derived from the Constitution,’ the liberty rights protected by procedural due process are somewhat broader”¹² *Rees v. Office of Children & Youth*, 744 F. Supp. 2d 434, 456 (W.D. Pa. 2010), *aff’d*, 473 F. App’x 139 (3d Cir. 2012) (internal citations omitted). We suspect that a court would engage in some sort of procedural due process analysis here, particularly with respect to the withdrawal of ventilators, if only because withdrawing a ventilator might lead to the patient’s death. *See Rotunda & Nowak, supra*, at § 17.3(b) (noting that a “procedural due process issue would arise if the government were to authorize the removal of life support systems where the patient has not made such a request”).

“The fundamental requirement of due process is the opportunity to be heard ‘at a meaningful time and in a meaningful manner.’” *Mathews*, 424 U.S. at 333 (quoting *Armstrong v. Manzo*, 380 U.S. 545, 552 (1965)). Due process is a “flexible concept that varies with the particular situation,” *Zinermon v. Burch*, 494 U.S. 113, 127 (1990), and the adequacy of the procedures depends on a balancing of three factors: (1) “the private interest that will be affected by the official action;” (2) the “risk of an erroneous deprivation of such interest through the procedures used, and the

¹² The Supreme Court is apparently divided on whether a liberty interest derived from the Constitution must also be a “fundamental right” for any procedural due process protections to attach. *See Kerry v. Din*, 135 S. Ct. 2128, 2142-43 (2015) (Breyer, J., dissenting) (contrasting, along with three other justices, liberty interests that warrant procedural due process protections from fundamental rights under substantive due process); *id.* at 2137 (opinion of Scalia, J.) (criticizing, along with two other justices, Justice Breyer’s argument that “there are two categories of implied rights protected by the Due Process Clause: really fundamental rights, which cannot be taken away at all absent a compelling state interest; and not-so-fundamental rights, which can be taken away so long as procedural due process is observed”).

probable value, if any, of additional or substitute procedural safeguards;” and (3) “the Government’s interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.” *Mathews*, 424 U.S. at 335.

Applying this balancing test here, the private interest and the governmental interest are both strong. It is difficult to imagine a more important private interest: the removal of a patient from a ventilator (or the decision not to place the patient on a ventilator in the first place) may well result in the patient’s death. At the same time, the Government needs the hospital to make allocation decisions quickly to achieve its similarly important interest in saving lives. If the hospital must follow complicated, lengthy procedural requirements before making allocation decisions, then patients might die while waiting for a ventilator. Similarly, if the hospital or the government has to devote staff to help implement the procedural safeguards, those employees will not be available to respond to the emergency in other ways. Finally, with respect to the remaining factor, it is difficult to know the risk of erroneous deprivation without first knowing what the criteria will be. There will be relatively little risk of error if the criteria are clear, objective, and easy-to-administer, but the risk will be much greater if they are complicated or allow for considerable discretion.

The entities that have already formulated allocation criteria seem to have arrived at a consensus about some minimum procedural safeguards. *See, e.g.,* CDC Ventilator Document Workgroup, *supra*, at 21. First, the State should employ clear, objective criteria that provide advance notice about the standards that will be applied and should also ensure that there will be transparency in the process for formulating and implementing the standards. *See id.* Second, allocation decisions should be made by a neutral decisionmaker, like an independent triage specialist, instead of the patient’s attending physician, who may have a conflict of interest. *See* New York Guidelines at 37-38; *see also* Code of Medical Ethics, *Opinion 2.03 – Allocation of Limited Medical Resources* (“The treating physician must remain a patient advocate and therefore should not make allocation decisions.”). Third, the hospital should give notice to patients when they are denied a ventilator or before they are withdrawn from a ventilator and explain the reasons for that decision, including how the allocation criteria operate and how they were applied in the particular patient’s case.

The more difficult question is whether a hospital will have to provide some form of appeal before a patient is withdrawn from a ventilator. “In extraordinary or emergency situations, . . . due process may only require a hearing *after* the government action is taken.” *Aminoil, Inc. v. Env’tl. Prot. Agency*, 599 F. Supp. 69, 74 (C.D. Cal. 1984) (emphasis added). The government interest in responding quickly to the crisis exceeds usually the private interest at stake, and the government therefore may typically provide a post-deprivation hearing. See, e.g., *Boddie v. Connecticut*, 401 U.S. 371, 379 (1971) (explaining that “extraordinary situations” may exist “where some valid governmental interest is at stake that justifies postponing the hearing until after the event”). But it is not clear that a post-deprivation hearing will suffice for patients being removed from a ventilator. “[T]he fundamental requirement of due process is the opportunity to be heard at a *meaningful* time and in a *meaningful* manner.” *Mathews*, 424 U.S. at 333 (internal quotation marks omitted; emphasis added). A post-deprivation hearing will not be very meaningful if the patient is likely to die soon after the ventilator is withdrawn.

Perhaps for this reason, the United States Department of Veterans Affairs (“VA”) has decided to offer a “real-time clinical appeals process” for at least some ventilator allocation decisions in its own medical facilities. Pandemic Influenza Ethics Initiative Work Group, Veterans Health Administration, *Meeting the Challenge of Pandemic Influenza: Ethical Guidance for Leaders and Healthcare Professionals in the Veterans Health Administration*, at 39 (2010), available at www.ethics.va.gov/activities/pandemic_influenza_preparedness.asp (last visited Dec. 10, 2015). The VA’s guidance provides for “rapid review” of certain types of claims that the triage officer misapplied the applicable procedures, which suggests a form of pre-deprivation review. *Id.* New York has similarly recommended “real-time individual case appeals” for a limited category of “procedural” or “technical” errors, such as “when a withdrawal decision was made without considering all relevant clinical triage criteria,” noting that the appeals might be necessary to comply with due process. New York Guidelines at 234.

If a rapid review system is workable, a court would probably require some form of pre-deprivation review along the lines suggested by the VA and New York before a patient is removed from a ventilator. Due process is a “flexible concept,” *Zinerman*, 494 U.S. at 127, and if the criteria are based on some sort of numerical score, it would probably suffice to give patients an

opportunity to challenge the way that the score was calculated or other similar procedural errors.

However, there is significant disagreement among experts about the workability of such an approach. “An on-going appeals process will require significant time and personnel, both of which may be in short supply during an influenza pandemic.” New York Guidelines at 233. It might also “create unreasonable delays in implementing triage decisions,” thereby undermining the State’s goal of saving lives. *Id.* Some commentators have instead suggested a retrospective review of all triage decisions to “provide oversight and accountability” for the process and to ensure that the criteria are being followed. *Id.* at 233-34. Because the government has a strong interest in ensuring that allocation decisions can be made quickly enough so that patients who are likely to benefit from treatment will not die waiting for a ventilator, a court would consider those concerns. Thus, if the experts working on draft criteria in Maryland determine that a pre-deprivation appeals process would be unworkable, it is at least possible that the State might satisfy due process even without offering a pre-deprivation appeal.

C. Health Care Workers’ Immunity from Liability

Your last question is whether a hospital or clinician would risk liability if, under State-adopted criteria for the allocation of ventilators, the hospital removed a patient from a ventilator to make the device available to another patient. The Maryland Catastrophic Health Emergencies Act specifically addresses this issue: “A health care provider is immune from civil or criminal liability if the health care provider acts in good faith and under a catastrophic health emergency proclamation.” PS § 14-3A-06. “Health care provider” means “(1) a health care facility as defined in § 19-114(d)(1) of the Health-General Article; (2) a health care practitioner as defined in § 19-114(e) of the Health-General Article; and (3) an individual licensed or certified as an emergency medical services provider under § 13-516 of the Education Article.” PS § 14-3A-01(e)(1)-(3).

The purpose of this immunity provision is to ensure that clinicians can comply with the Governor’s orders and act to save lives during a public health emergency without fear of liability. “Evidence shows that some clinicians will not participate fully, or at all, if they fear liability for their actions that result in unintentional harm to patients or even from foreseen harms that

result from following appropriately vetted clinical guidelines for [mass critical care].” Brooke Courtney et al., *Legal Preparedness: Care of the Critically Ill and Injured During Pandemics and Disasters: CHEST Consensus Statement*, 146:4 Supp. CHEST J. e134S, at e139S (2014). For this reason, the predecessor of § 14-3A-06 was added after the Association of Maryland Hospitals & Health Systems (“MHA”) objected to the failure of the original bill to include an immunity provision. MHA argued that “providers need liability protection for carrying out the Governor’s orders so there is no delay or questions surrounding compliance.” *Hearing on S.B. 234 Before the Educ., Health, & Envtl. Affairs Comm.*, 2002 Leg., Reg. Sess. (Feb. 6, 2002) (written testimony of MHA).

Taken together, the plain language of § 14-3A-06 and its broad legislative purpose indicate that health care providers would be immune from civil or criminal liability if, in keeping with State-mandated allocation criteria, they removed a patient from a ventilator. A provider is immune if acting “in good faith and under a catastrophic health emergency proclamation.” PS § 14-3A-06. Under Maryland law, “good faith” typically means “an intangible and abstract quality that encompasses, among other things, an honest belief, the absence of malice and the absence of design to defraud or to seek an unconscionable advantage.” *Rite Aid Corp. v. Hagley*, 374 Md. 665, 680-81 (2003) (quoting *Catterton v. Coale*, 84 Md. App. 337 (1990)); see also *Black’s Law Dictionary* 808 (10th ed. 2004) (defining “good faith” as, among other things, “[a] state of mind consisting in (1) honesty in belief or purpose [and] (2) faithfulness to one’s duty or obligation”). A health care provider who acts in accordance with State-required allocation criteria will thus almost by definition be acting in good faith, regardless of the negative consequences arising from the withdrawal of a patient’s ventilator.¹³

¹³ Hospital physicians and staff would likely also be entitled to immunity if they act in accordance with State-established criteria that are voluntary. For immunity to attach under the Public Safety Article, the health care provider’s actions must be taken “in good faith” and “under a catastrophic health emergency proclamation,” PS § 14-3A-06, neither of which depends on the criteria being mandatory. As for actions taken pursuant to DHMH’s authority to publish protocols for catastrophic health emergencies under HG § 18-903, a health care provider acting “in good faith” and “in accordance with a catastrophic health emergency disease surveillance and response program” is immune from civil or criminal liability “unless the health care provider acts with willful misconduct.” HG § 18-907(f). This statute too would likely provide immunity for actions taken in accordance with non-binding guidelines.

A number of commentators agree with this reading of the statute. Scholars have described Maryland as having “exceptionally good protections that are directly applicable to crisis standards of care and the allocation of ventilators.” Mareiniss et al., *ICU Triage*, *supra*, at 332; *see also* Valerie Gutmann Koch, *Unique Proposals for Limiting Legal Liability and Encouraging Adherence to Ventilator Allocation Guidelines in an Influenza Pandemic*, 14 DePaul J. Health Care L. 467, 488 n.98 (2013) (citing Maryland as an example of a State with the “most broad immunity-conferring legislation currently in effect”). As one set of experts explained, “it is likely that [Maryland] providers would be protected if they used an ICU allocation protocol issued or endorsed by the state during such a declared emergency to make triage decisions as this could be considered acting in good faith.” Mareiniss et al., *ICU Triage*, *supra*, at 335.

For the sake of completeness, we note one complicating factor. The statute as originally enacted in 2002 stated that “[a] health care provider acting in good faith and in accordance with a catastrophic health emergency proclamation is immune from civil or criminal liability related to those actions, *unless the health care provider acts with willful misconduct*.” 2002 Md. Laws, ch. 1 (emphasis added, codified at Ann. Code Md., art. 41 § 2-202(g) (2003 Repl. Vol. 2)); *see also* HG § 18-907(d) (enacted as part of the same legislation and providing identical immunity for actions taken in accordance with DHMH’s “catastrophic health emergency disease surveillance and response program”). During the 2004 creation of the Public Safety Article, the General Assembly amended the provision by, among other things, removing the phrase referring to “willful misconduct.” 2004 Md. Laws, ch. 26 at 198 (codified at PS § 14-3A-06). The accompanying Revisor’s Note explains that the new language was “derived without substantive change,” but does not mention this particular amendment. *Id.*, § 2 (Revisor’s Note to PS § 14-3A-06).

When statutory language is deleted during code revision without comment, we ordinarily regard the amendment as non-substantive and interpret the new language in a manner that is consistent with its pre-amendment meaning. *See, e.g., Allen v. State*, 402 Md. 59, 71-72 (2007). But some public health officials have suggested that knowingly withdrawing or withholding life support begins to tread the line of “willful misconduct.” Mareiniss, Levy & Regan, *ICU Triage*, *supra*, at 333. We doubt that is the case, *see* New York Guidelines at 225 n.118 (concluding that removing a patient from a ventilator pursuant to State-issued

guidelines would not be misconduct of any kind), but if so, the deletion of the language would seem to be the type of change that would have merited comment. After all, the Revisor’s Note *does* comment on another, seemingly much less substantive change. *See, e.g.*, 2004 Md. Laws, ch. 26 § 2 (Revisor’s Note to PS § 14-3A-06) (noting that the phrase “related to those actions,” which appeared in the prior version of the statute, was “deleted as implicit in the structure of the revision”).

Nonetheless, we think that the most logical way to interpret the amendment, given the revision committee’s failure to comment, is that the General Assembly viewed the “willful misconduct” exception as surplusage in light of the existing “good faith” requirement. In other words, the General Assembly apparently did not think it was possible for a health care provider to act with willful misconduct if he or she was acting “in good faith and under a catastrophic health emergency proclamation.” PS § 14-3A-06. In fact, in a different section of the Public Safety Article, the Legislature specifically explained that, for purposes of liability of officers or emergency responders under the Maryland Emergency Management Assistance Compact, “[g]ood faith” already requires an individual to act without “willful misconduct.” PS § 14-803(4)(d)(3) (“Good faith in this [article 4 of the Compact] shall not include willful misconduct, gross negligence, or recklessness.”). “When a statute’s language is clear and unambiguous,” as it is here, “we need look no further for some hidden legislative intent.” *Abramson v. Montgomery County*, 328 Md. 721, 736 (1992). Based on this plain language, it is our view that health care providers are immune from civil or criminal liability when withdrawing and reallocating ventilators in accordance with State-adopted allocation criteria during a catastrophic health emergency.

III

Conclusion

In our opinion, the Governor has the authority to issue mandatory criteria governing the allocation of ventilators during a flu pandemic if he has declared a catastrophic health emergency. A reviewing court would likely scrutinize those criteria to ensure that they comport with due process but likely would not strike down the criteria if the State has crafted them with care. We further conclude that a medical provider who follows the criteria in good faith is immune from liability.

Brian E. Frosh
Attorney General of Maryland

Patrick B. Hughes
Assistant Attorney General

Adam D. Snyder
Chief Counsel, Opinions & Advice

* Andrew Gear, a former intern in this office, assisted in the preparation of this opinion.